Ariel Med Distribution 1-800-323-6070

The COVID19 IgG/IgM Rapid Response Test Kit

The COVID19 IgG/IgM Rapid Response Test Kit, manufactured by Phamatech, Inc. (San Diego, CA), is a 10-minute instant point-of-care test device for the qualitative detection of IgG and IgM antibodies specific to the 2019-nCoV in human whole blood, serum or plasma.

Important

- This test is 98.6% accurate for detection of the IgM antibodies specific to 2019-nCoV
- This test is 93% accurate for detection of the IgG antibodies specific to 2019-nCoV
- This test was developed in Belgium and is manufactured in the USA - San Diego, CA.
- THE USFDA updated their guidance, issued on March 16, 2020, to allow the distribution of this product for use by Healthcare worker, at point-of-care facilities and for diagnostic use in laboratories during the COVID19 pandemic.
- All Test results are presumptive and should be confirmed by an approved molecular assay. A presumptive negative test does not preclude the 2019n-CoV infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, a presumptive positive result does not rule out infections caused by other viruses.
- If you get positive antibodies then you still need the swab (PCR) to make sure you are not a carrier.

Phamatech's "*2019-nCoV IgG/IgM Rapid Test*" is an in vitro test for the qualitative detection of IgG and IgM antibodies specific to 2019-nCoV in human whole blood, serum or plasma specimen. A whole blood sample can be collected from a finger prick using a single-use disposable lancet, then add to the test device, which will provide visual results in 10 minutes.

The test is an easy-to-use on-site test which does not require any instruments or refrigeration. The test can be used in emergency room, physician's offices, nurses' stations, medical clinics, pharmacies, drive through test stations, and even in-home setting to identify if symptomatic patients may be infected with COVID19.

Positive results of IgG/IgM antibodies indicate current and/or past exposure to COVID19.

Negative results indicate that the patient currently has not produced antibodies against COVID19.

Clinical testing has been performed in China against COVID19 infected and normal patients with 99% Relative Sensitivity, 98% Relative Specificity, and 98.6% Accuracy results for IgG; and 85% Relative Sensitivity, 96% Relative Specificity, and 93% Accuracy for IgM.

Phamatech's "*2019-nCoV IgG/IgM Rapid Test*" is recommended for professional use in conjunction with clinical evaluation and results should be confirmed by other approved testing methods as required by CDC.

HOW THE TEST WORKS

In response to the global pandemic caused by 2019n-CoV (COVID19), the COVID19 IgG/IgM Rapid Test Cassette was developed as a 10-minute simple field test using a lateral flow immunoassay that will allow field personnel with minimal training to perform. The test detects the presence of IgG and IgM antibodies specific to 2019n-CoV (detected in China in 2019) generally available in whole blood / serum / plasma after infection by 2019n-CoV.

The COVID19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based, lateral flow immunoassay for the detection of IgG and IgM antibodies to 2019-nCoV in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component.

In the IgG component, anti-human IgG is coated in the IgG test line region on the membrane. During testing, when the specimen is added to the test cassette, it reacts with 2019-nCoV antigen-coated particles inside the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG coated in the IgG test line region. If the specimen contains IgG antibodies to 2019-nCoV, a complex will be formed resulting in a colored line that will appear in the IgG test line region. Similarly, anti-human IgM is coated in the IgM test line region and if the specimen contains IgM antibodies to 2019-nCoV, the conjugate-specimen complex reacts with anti-human IgM on the membrane. A colored line appears in IgM test line region as a result.

Therefore, if the specimen contains 2019-nCoV IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains 2019-nCoV IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain 2019-nCoV antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred, and the test has been activated correctly.

THE REAGENTS

The test contains anti-human IgM and anti-human IgG as the capture reagent, 2019-nCoV antigen as the detection reagent. A goat anti-mouse IgG is employed in the control line system.

PRECAUTIONS

1. **Biohazard**. Biological samples such as blood have the potential to transmit infectious diseases. Follow all applicable local, state, and federal regulations.
2. Use routine laboratories precautions. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use the test if protective pouch is damaged.
4. For research use only. Do not use after expiration date.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Please ensure that an appropriate amount of samples are used for testing. Too much or too little of sample size may lead to deviation of results.
8. Used test should be discarded according to local regulations.
9. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

PROCEDURE

SPECIMEN COLLECTION AND PREPARATION FOR TESTING

The COVID19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or finger prick), serum or plasma.

To collect Finger prick Whole Blood Specimens (when ready to perform the test):

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin of 1 finger with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Collect the blood from the finger using the dropper provide or by using a capillary tube.
- Transfer the blood specimen to the sample well on the test device

To collect Whole Blood using Venipuncture and preparation of Serum and Plasma:

- Collect blood using general guideline for venipuncture.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.

Testing Preparation

- Testing should be performed immediately after the specimens have been collected.
- Do not leave the specimens at room temperature for prolonged periods.
- Serum and plasma specimens may be stored at 2-8°C for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20°C.
- Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- Whole blood collected by finger prick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

RUNNING THE TEST

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

- To use a dropper: Hold the dropper vertically, draw the specimen to the **fill line** (approximately 10μL), and transfer the specimen to the specimen well (**S**), then add **2 drops of buffer** (approximately 80 μL), and start the timer.
- To use a pipette: Transfer **10 μL** of specimen to the specimen well(**S**), then **add 2 drops of buffer** (approximately 80 μL), and start the timer

For **Venipuncture Whole Blood** specimen:

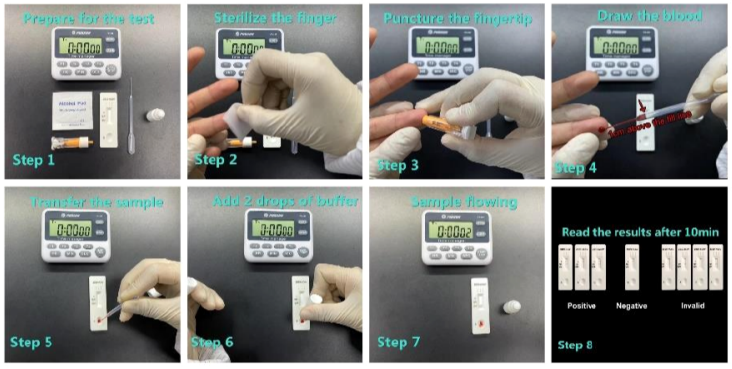
- To use a dropper: Hold the dropper vertically, draw the specimen about **1 cm above the fill line** and transfer **1 full drop** (approx. 20μL) of specimen to the sample well(**S**). Then add **2 drops of buffer** (approximately 80 μL) and start the timer.
- To use a pipette: Transfer **20 μL** of whole blood to the specimen well(**S**), then **add 2 drops of buffer** (approximately 80 μL), and start the timer

For **Finger prick Whole Blood** specimen:

- To use a dropper: Hold the dropper vertically, draw the specimen about **1 cm above the fill line** and transfer **1 full drop** (approx. 20μL) of specimen to the sample well(**S**). Then add **2 drops of buffer** (approximately 80 μL) and start the timer.
- To use a capillary tube: Fill the capillary tube and transfer **approximately 20μL of finger prick whole blood specimen** to the specimen well (**S**) of test cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.

Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS

IgG POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.

IgM POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.

IgG and IgM POSITIVE:* Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of 2019-nCoV (COVID19) antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the IgG region and IgM region.

INVALID: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

- ***All test results are presumptive and should be confirmed by an approved molecular assay.***
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- Results from an antibody test should not be used as the sole basis to diagnose or exclude SARS-CoV-2 (COVID-19) infection or to inform infection status.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The COVID19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to 2019-nCoV in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to 2019-nCoV can be determined by this qualitative test.
2. The COVID19 IgG/IgM Rapid Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to 2019-nCoV in the specimen and should not be used as the sole criteria for the diagnosis of 2019-nCoV infections.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of 2019-nCoV infection.
5. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.
6. The test will show negative results under the following conditions: The titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the novel coronavirus antibody has not appeared at the time of sample collection (Asymptomatic stage).

PERFORMANCE CHARACTERISTICS

Clinical Performance

The clinical performance of the "*COVID19 IgG/IgM Rapid Test Cassette*" was evaluated in Shanghai, China with clinical samples derived from blood samples collected from 2019n-CoV infectious patients and 2019n-CoV non-infectious patients confirmed by PCR.

The study included testing of 20 known positive samples and 50 known negative samples.

Of the 20 known positive samples, the IgG test yields a 100% agreement of 20 out of 20, while the IgM test yields an 85% agreement of 17 out of 20.

Of the 50 known negative samples, the IgG test yields a 98% agreement of 49 out of 50, while the IgM test yields a 96% agreement of 48 out of 50. The data are illustrated in the table below.

Sensitivity and Specificity

IgG Result

Method		**PCR**		**Total Results**
	Results	**Positive**	**Negative**	
2019-nCoV IgG/IgM Rapid Test	Positive	20	1	21
	Negative	0	49	49
Total Result		20	50	70

IgG test results yields 20 positive results from 20 know positive samples.

IgG test results yields 49 negative samples from 50 known negative samples.

Relative Sensitivity: 100% (95%CI*: 86.0%-100%) *Confidence Interval

Relative Specificity: 98.0% (95%CI*: 89.4%-99.9%)

Accuracy: 98.6% (95%CI*: 92.3%-99.96%)

IgM Result

Method		**PCR**		**Total Results**
	Results	**Positive**	**Negative**	
2019-nCoV IgG/IgM Rapid Test	Positive	17	2	19
	Negative	3	48	51
Total Result		20	50	70

IgM test results yields 17 positive results from 20 know positive samples.

IgG test results yields 48 negative samples from 50 known negative samples.

Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%) *Confidence Interval

Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)

Accuracy: 92.9% (95%CI*: 84.1%-97.6%)

Cross-reactivity

The "*COVID19 IgG/IgM Rapid Test Cassette*" (Whole Blood/Serum/Plasma) has been tested against anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

- Triglyceride: 50 mg/dL - Ascorbic Acid: 20mg/dL - Hemoglobin: 1000mg/dL-
Bilirubin: 60mg/dL - Total cholesterol : 6mmol/L

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